

IX. SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 17 2003

SUBMITTER: United States Surgical,
a division of Tyco Healthcare Group, LP
150 Glover Avenue
Norwalk, CT 06856

CONTACT PERSON: Robert Zott

DATE PREPARED: August 21, 2003

CLASSIFICATION NAME: Absorbable poly(glycolide/L-lactide)
surgical suture

COMMON NAME: Surgical Suture

PROPRIETARY NAME: Caprosyn* Absorbable Surgical Suture

PREDICATE DEVICES: K013671: L-25 Absorbable Suture

INDICATIONS: The device is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neurological surgery, or microsurgery.

MATERIALS: Glycolide, Caprolactone, Tri-Methylene Carbonate, and Lactide polymers.

**DEPARTMENT OF HEALTH & HUMAN SERVICES****Public Health Service**

**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850**

NOV 17 2003

Mr. Robert Zott
Regulatory Affairs Program Manager
United States Surgical
Tyco Healthcare
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K032586

Trade/Device Name: Caprosyn Absorbable Surgical Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: October 22, 2003
Received: October 27, 2003

Dear Mr. Zott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Probst
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

III. INDICATIONS FOR USE

510(k) Number (if known): K032586

Device Name: Caprosyn* Absorbable Surgical Suture

Indications For Use:

Caprosyn* synthetic absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neurological surgery, or microsurgery.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032586